IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: ***Melissa and Eric Ridgley v. Ethicon, Inc. et al.*** **Case No. 2:12-cv-1311**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFF'S MEMORANDUM IN RESPONSE AND OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Plaintiffs Melissa Ridgley and Eric Ridgley, by and through their counsel, hereby respond to Defendants' Motion for Summary Judgment. In support of their response and opposition to Defendant's Motion, Plaintiffs state as follows:

INTRODUCTION

Defendant Ethicon is not entitled to summary judgment because the Ridgleys have more than adequately demonstrated that there are multiple genuine issues that are more appropriately assessed by a jury, and therefore are not yet ripe for determination at this stage of the litigation.

SUMMARY JUDGMENT STANDADRD

Summary judgment can be granted only when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter

of law." Fed. R. Civ. P. Rule 56(c). In considering a motion for summary judgment, the "Court must view the evidence in a light most favorable to the nonmovant and draw all reasonable inferences in its favor[.]" *SRI Int'l v. Matsushita Electric Corp. of America*, 775 F.2d 1107, 1116 (Fed. Cir. 1985). The Court must also "resolve all doubt over factual issues in favor of the party opposing summary judgment[.]" *Id*. On summary judgment, the "movant bears the burden of demonstrating absence of all genuine issues of material fact[.]" *Id*.

Here, Defendants' Motion for Summary Judgment contends, in part, that Plaintiffs have come forth with "no evidence that any allegedly deficient warning caused [Mrs. Ridgley's] claimed injuries." Defendants' Motion for Summary Judgment, p. 8. By asserting such an unequivocal position, Plaintiffs need only provide some evidence that, viewed in a light most favorable to Plaintiffs, would demonstrate a factual dispute concerning this issue. The evidence presented herein more than meets this threshold.

I. Plaintiffs Have Come Forth With Evidence Sufficient to Support Causes of Action Sounding in Negligence, Defective Design, Defective Manufacturing, Failure to Warn, Breach of Express And Implied Warranties, And Loss of Consortium.

Defendants' Motion for Summary Judgment attempts to weave its way through a minefield of its own willful, wanton, and fraudulent conduct stemming from its decision to conceal and/or omit safety information vital to its customers' health. Defendants' dangerous business model of deceit and omission resulted in thousands of serious injuries suffered by innocent women throughout the United States, including Mrs. Ridgley. This conduct – including the aggressive marketing of inadequately-tested and defective products while hiding and obscuring known safety issues – was unlawful pursuant to both Indiana common law and the Indiana Product Liability Act ("IPLA").

Both Indiana common law and the IPLA have recognized pleading standards which Plaintiffs' evidence more than satisfies. The United States District Court for the Northern District of Indiana explained the relationship between common law and IPLA:

> While the Defendant is correct that IPLA subsumes both strict liability and negligence actions, *see Gardner v. Tristar Sporting Arms, Ltd.*, No. 1:09-CV-0671, 2010 WL 3724190, at *2 (S.D. Ind. Sept. 15, 2010), dismissal is improper here. First, when viewing the allegations in a light most favorable to the non-movant, the Plaintiff has satisfied the general pleading standards by stating a plausible claim for relief—namely, that he suffered physical harm due to the Defendant's defective product

Lyons v Leatt Corp., 2015 US Dist LEXIS 152015 (ND Ind Nov. 10, 2015, No. 4:15-CV-17-TLS)

By way of example, to survive summary judgement in a failure to warn case based in negligence, there must be a genuine issue as to whether the defendant: (1) supplied a product with a concealed danger; (2) knew or had reason to know of the danger; (3) failed to adequately warn of the danger; and must prove (4) that the failure to warn was a proximate cause of injuries. *See e.g.*, *In re Inlow Acc. Litig.*, 2002 US Dist LEXIS 8318, at *37-40 (SD Ind Apr. 16, 2002, Cause No. IP 99-0830-C H/K); *Lucas v. Dorsey Corp*., 609 N.E.2d 1191, 1198 (Ind. App. 1993).

Pursuant to IPLA, failure to warn claims require genuine issues as whether: (i) the defective product was unreasonably dangerous; (ii) the defect existed at the time the product left the defendant's control; (iii) the product was expected to, and did, reach the consumer without substantial alteration; and (iv) the plaintiff's injuries were proximately caused by the defect in the product. *See* Ind. Code §§ 33-1-1.5-1 et seq.; *Moss v. Crosman Corp*., 136 F.3d 1169, 1171 (7th Cir. 1998) (internal citation omitted) (noting a "defective" product could be considered a fifth element).

According to the IPLA, a product is defective if a manufacturer failed to give appropriate warnings about how to use it and the product is unreasonably dangerous if it causes unexpected

injury. *See* Ind. Code § 33-1-1.5-2(7) and 5-2.5(b); *In re Inlow Acc. Litig.*, 2002 US Dist LEXIS 8318; *Anderson v. P.A. Radocy & Sons, Inc*., 67 F.3d 619, 624-26 (7th Cir. 1995).

Indiana law holds that a manufacturer has a duty to warn of latent defects in its products. See e.g., *In re Inlow Acc. Litig.*, 2002 US Dist LEXIS 8318; *Ritchie v. Glidden Co*., 242 F.3d 713, 720-21 (7th Cir. 2001) (applying Indiana law). The duty to warn consists of two duties: (i) to provide adequate instructions for safe use, and (ii) to provide a warning as to dangers inherent in improper use. *Natural Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 161 (Ind. App. 1997). If a duty to warn exists, a manufacturer has a duty to warn those persons it should reasonably foresee would be likely to use its product or who are likely to come into contact with a latent danger inherent in the product's use. *See id*. at 162.

Here, Defendants have conceded they had a duty to warn. Defendants' contention is that their duty to warn was obviated because: (i) the dangers inherent in its TVT mesh product were so widely disseminated and universally known as to be common knowledge in the industry; or (ii) that Defendants' warnings disseminated to Mrs. Ridgley's doctor accounted for all Mrs. Ridgley's injuries triggered the "learned intermediary defense" which imputes those warnings to her. *See* Defendants' Motion for Summary Judgment, p. 9. In other words, the issue presented by Defendants' Motion for Summary Judgment is not whether Defendants had a duty to warn but rather whether Defendants' warnings were adequate.

As discussed further herein, Plaintiffs' have come forth with expert testimony regarding the insufficiency of Defendants' warnings provided to treating physicians, such as Mrs. Ridgley's surgeons, regarding the known dangers associated with Defendants' TVT mesh product. However, the controlling issue is whether the sufficiency of warnings is an appropriate inquiry at the summary judgment stage. According to the case law discussed below, the courts of Indiana and

the Seventh Circuit have held such an inquiry is a factual issue properly submitted to a jury. See e.g., *Jarrell v. Monsanto Co*., 528 N.E.2d 1158, 1162 (Ind. Ct. App. 1988) ("The question of duty is one of law while the question of the exercise of due care is one of fact. Thus, it is for the jury to determine whether or not a warning was required in order for defendant to discharge his duty of exercising due care.").

1. The IPLA Recognizes a cause of action stemming from a failure to warn and Plaintiff's evidence far exceeds the required showing.

Pursuant to the IPLA a product is defective if the seller/manufacturer fails to (i) properly package or label a product including reasonable warnings of known dangers, or (ii) give reasonably complete instructions on proper use of the product when the seller, by exercising reasonable diligence, could have made such warnings or instructions available to the user or consumer. *See* § 34-20-4-2. This required duty to warn is based on the public policy presumption that a manufacturer should have superior knowledge of its products. *See Smock Materials Handling Co. v. Kerr*, 719 N.E.2d 396, 403 (Ind. Ct. App. 1999) (citing *Natural Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 163 (Ind. Ct. App. 1997)). As such, a manufacturer has a duty to warn with respect to latent dangerous characteristics of the product, even if there is no independent "defect" in the product itself. *See Natural Gas Odorizing, Inc*., 685 N.E.2d at 161. Pursuant to Indiana law, a manufacturer is liable if it puts a product into the stream of commerce without adequate warnings that could reasonably have been given, if the lack of such warnings rendered the product unreasonably dangerous for its expected use. *Downs v. Panhandle E. Pipeline Co*., 694 N.E.2d 1198, 1211 (Ind. Ct. App. 1998) (citing *Jarrell v. Monsanto Co*., 528 N.E.2d 1158, 1166 (Ind. Ct. App. 1988)). A manufacturer, seller, or distributor of a product has a duty to warn those persons who would reasonably be likely to use its product or who are likely to come into contact with the

danger inherent in the product's use. *Ford Motor Co. v. Rushford*, 868 N.E.2d 806, 810-11 (Ind. 2007).

Failure to warn is a theory of recovery that is separate from a claim alleging defective design. *Minisan v. Danek Med., Inc.*, 79 F.Supp. 2d 970 (N.D. Ind.1999) (citing *Gorton v. Am. Cyanamid Co*., 533 N.W.2d 746 (Wis. 1995)). In a failure to warn case, the plaintiff is not required to establish that he/she would have read the warning and taken the steps to avoid injury. *Kovach*, 913 N.E.2d at 199.

A product may be defective and unreasonably dangerous as a result of deficient or inadequate warnings. Even if the product is faultless in design, material, and workmanship, if a reasonably prudent person would require a warning, the product can be deemed defective solely because of a failure to supply adequate warnings with regard to potential dangers. *Ward & Co. v. Gregg*, 554 N.E.2d 1145, 1162 (Ind. Ct. App. 1990).

Here, Defendants' TVT mesh product was defective in its design in addition to the lack of sufficient warnings regarding known dangers. Plaintiffs have come forth with expert testimony from Dr. Konstantin Walmsley ("Dr. Walmsley") in which he unequivocally states as follows: "It is my opinion that the IFU [Instructions for Use] for the TVT in 2010 was not sufficient to enable informed consent from the patient." Ex. A, Report of Pls.' Expert Dr. Konstantin Walmsley, General Opinion No. 1. Dr. Walmsley's report goes on to explain:

> The TVT IFU does not mention: mesh contraction; the severity of mesh-related dyspareunia; mesh shrinkage. [ ] In my opinion, a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events or the particular role mesh plays in mediating these adverse events."

Id.

Defendants contend its warnings were adequate and, as a result, the case should be summarily dismissed. The conflicting evidence and contentions between Plaintiffs and Defendants on this issue establishes the existence of a genuine issue of material fact regarding the adequacy of Defendants' warnings. This genuine issue of material fact is sufficient, on its own, to support the denial of Defendants' Motion for Summary Judgment.

However, the adequacy of warnings is properly a question of fact for the jury and not an inquiry ripe for an ultimate determination at the summary judgment stage of this litigation.

2. The Adequacy of Warnings is a Question of Fact Reserved for the Jury and, thus, Inappropriate for Summary Judgment.

As previously discussed, Defendants do not contest that they had a duty to warn. The learned intermediary defense raised by Defendants presumes a duty to warn and argues that the warnings communicated to the prescribing doctor are imputed to the patient.

However, Defendants failed to inform this Court that the Indiana Court of Appeals held that the "adequacy of warnings is classically a question of fact reserved to the trier of fact and, therefore, an inappropriate matter for summary judgment," *Jarrell v. Monsanto Co*., 528 N.E.2d 1158, 1162 (Ind. Ct. App. 1988) ("The question of duty is one of law while the question of the exercise of due care is one of fact. Thus, it is for the jury to determine whether or not a warning was required in order for defendant to discharge his duty of exercising due care.").

Knowing that they cannot argue the adequacy of their warnings at the summary judgment stage, Defendants argue that the learned intermediary doctrine "discharges" their duty to warn. Defendants' Motion for Summary Judgment, p. 9. However, Defendants' duty to warn is not discharged pursuant to the leaned intermediary defense. If applicable, the learned intermediary defense would potentially transfer the recipient of Defendants' duty to warn from the patient to

the treating physician. As discussed above, Plaintiffs' have come forth with expert testimony sufficient to raise a genuine issue regarding the adequacy of Defendants' warnings.

However, Defendants' contention that their duty was discharged conflicts with the Third Restatement, Section 6(d), which explicitly includes the learned intermediary doctrine:

> A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
>
> (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
>
> (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings

The learned intermediary defense does not contemplate the discharge of a defendant's duty to warn. Rather, the theory is that in certain circumstances the duty is owed to the prescribing doctor in lieu of the patient. This transfer of the duty's recipient does nothing to diminish the need for adequate and reasonable warnings.

A defendant relying on the learned intermediary defense will ultimately be required to come forth with a showing that its warnings were reasonable and adequate. But that will be a determination for the trier of fact and it is not an appropriate inquiry at the summary judgement stage.

In addition to claiming their duty was discharged, Defendants contend that Mrs. Ridgley's doctor never relied on any information provided by Defendants regarding its products, which would include information provided by Defendants' employees, its traveling sales force, its marketing team, its physician trainers, or any of its promotional and educational materials. According to Defendants, Dr. Ridgley's surgeon gained her full expertise about Defendants' sophisticated, state-of-the-art medical device – including vital information about its physical

composition, implantation and extraction strategies, and all associated warnings, risks, and side effects – without relying on any information supplied by Defendant. Defendants go as far as to argue that the inherent risks in their TVT mesh product are so "obvious" that there was no reason to mention any of those risks to the doctors implanting the devices into patients. *Id*.

Defendants' contention make it difficult to fathom why any physician or patient aware of the inherent dangers of Defendants' TVT mesh product would ever consent to its use. For instance, Plaintiffs have alleged that Defendants breached its duty to warn by withholding or omitting the following adverse effects from both Mrs. Ridgley and her treating physician:

a. Defendants' TVT mesh products' ("Products" or "Medical Device") propensities to contract, retract, and/or shrink inside the body;
b. the Products' propensities for degradation, fragmentation and/or creep;
c. the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;
d. the rate and manner of mesh erosion or extrusion;
e. the risk of chronic inflammation resulting from the Products;
f. the risk of chronic infections resulting from the Products;
g. the risk of permanent vaginal or pelvic scarring as result of the Products;
h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Products;
i. the need for corrective or revision surgery to adjust or remove the Products;
j. the severity of complications that could arise as a result of implantation of the Products;
k. the hazards associated with the Products;
l. the Products' defects described herein;
m. treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;
n. treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;
o. treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;
p. use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;
q. removal of the products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and
r. complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

Plaintiffs' Complaint filed on April 26, 2012 ("Plaintiffs' Complaint"), p. 18-19.

Defendants counter that Mrs. Ridgley, and those similarly situated, were told that the surgery could cause a variety of symptoms, such as incontinence, leakage of urine, diminished sex life, and pain. Those, however, are generalized symptoms of potential injuries caused by Defendants' products. Plaintiff alleges that the warnings of urinary retention and pelvic pain, whether emanating from a doctor or Defendants, fell far short of the appropriate warnings of known dangers resulting from the following:

a. That the Medical Device was not as safe as other products and procedures available to treat incontinence and/or prolapse;
b. That the risk of adverse events with the Medical Device was higher than with other products and procedures available to treat incontinence and/or prolapse;
c. That the risk of adverse events with the Medical Device was not adequately tested and were known by Defendants;
d. That the limited clinical testing revealed the Medical Device had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;
e. That Defendants failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;
f. That Defendants were aware of dangers in its pelvic mesh products, including the pelvic mesh systems, in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;
g. That the pelvic mesh systems were dangerous and caused adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;
h. That patients frequently would need revisionary surgery due to changes in the structure of the Medical Device that would cause it to become loose, or shift position within the body.
i. That patients needed to be monitored more regularly than usual while using the Medical Device and that in the event the product needed to be removed that the procedure to remove them had a very high failure rate and/or needed to be performed repeatedly.

Id. at 10-11.

At trial, Plaintiffs will present additional evidence that merely providing a laundry list of possible symptoms is inadequate information for a patient to provide informed consent. But those arguments are not ripe at the summary judgment stage.

Plaintiffs' expert, Dr. Walmsley, has already issued a report supporting these allegations and, thereby, establishes a genuine issue of material fact regarding the adequacy of Defendants' warnings. At the summary judgment stage, this more than meets Plaintiffs' burden pursuant to Indiana law and Defendants' Motion for Summary Judgment should be denied.

3. Plaintiffs Have Established a Genuine Issue of Material Fact Regarding the Existence of a Safer and Feasible Alternative Design.

The relevant issue is whether Plaintiffs have come forth with evidence sufficient to raise a genuine issue of material fact as to whether a safer and feasible alternative design existed which could have prevented Mrs. Ridgley's injuries.

Pursuant to Indiana law, the existence of a "safer, feasible alternative" design is an element in a defective design cause of action. *Simmons v. Philips Elecs. N. Am. Corp.*, 2015 WL 1418772, at *10 (N.D. Ind. Mar. 27, 2015) (quoting *Whitted v. Gen. Motors Corp.*, 58 F.3d 1200, 1206 (7th Cir. 1995).

Indiana courts have further held that expert testimony is relevant and sufficient evidence to establish the alternative design prong of a defective design allegation. *See e.g., Dhillon v. Crown Controls Corp.*, 269 F.3d 865, 868 (7th Cir. 2001); *Piltch v. Ford Motor Co.*, 778 F.3d 628, 632 (7th Cir. 2015), *reh'g denied* (Apr. 1, 2015); *Pries v. Honda Motor Co.*, 31 F.3d 543, 546 (7th Cir. 1994).

Despite this relevant and admissible evidence, Defendants' insist that "Plaintiffs have produced no evidence that at the time Ms. Ridgley's TVT left Ethicon's control there existed an alternative design that was capable of preventing her alleged injuries." To reiterate, by asserting such an unequivocal position, Plaintiffs need only provide some evidence that, viewed in a light most favorable to Plaintiffs, would demonstrate a factual dispute concerning this issue. The evidence presented herein more than meets this threshold.

Here, Plaintiffs expert has already issued a report which states as follows: "Safer alternative designs and procedures existed in 2010 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy."

Defendants have cited three cases in support of their contention that this Court should summarily disregard Dr. Walmsley's expert opinion. Tellingly, none of the cases cited by Defendants analyze the IPLA or Indiana common law. And none of the opinions are from an Indiana court or even the Seventh Circuit. Two of the three cases apply Louisiana law and the third applies the law of Nevada.

By contrast, the cases cited above by Plaintiffs establishing the sufficiency of expert testimony regarding alternative designs are all from either an Indiana court or the Seventh Circuit and all apply the IPLA. Defendants' inability to cite a single case from the relevant jurisdiction or a single case applying the relevant statute illustrates the lack of legal support for Defendants' position.

Based on the discussion above, Plaintiffs have come forth with expert testimony sufficient to raise a genuine issue of material fact as to whether an alternative design was feasible relevant to the defective design inquiry pursuant to the IPLA.

4. Plaintiffs Have Established a Genuine Issue of Material Fact Regarding the Existence of a Manufacturing Defect.

Pursuant to Indiana law, strict liability applies against the manufacturer of a product or its defective component. *See* IPLA, Section 34-20-2-3. Indiana's strict liability doctrine is intended to deter manufacturers from producing products that are unreasonably dangerous to the foreseeable users of those products. *Guerrero v. Allison Engine Co.*, 725 N.E.2d 479, 482 (Ind. Ct. App. 2000) (citing *Maxon Corp. v. Tyler Pipe Indus., Inc.*, 479 N.E.2d 570, 578 (Ind. Ct. App. 1986)).

Although Indiana law does not require a manufacturer to produce accident-proof products, manufacturers are legally bound to design and build products which are reasonably fit and safe for their intended purpose. *See Liberty Mut. Ins. Co. v. Rich Ladder Co.*, 441 N.E.2d 996, 999 (Ind. Ct. App. 1982) (citing *Zahora v. Harnischfeger Corp*., 404 F.2d 172 (7th Cir. 1968)).

Plaintiffs have alleged that Defendants' TVT mesh product was not reasonably safe for their intended uses and were defective as a matter of law with respect to their manufacture, in that they deviated materially from Defendants' design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to Mrs. Ridgley and those similarly situated.

In support of these allegations, Plaintiffs have come forth with evidence from Dr. Walmsley's expert report which states that: (i) "Mrs. Ridgley's sling showed evidence of contraction and shrinkage;" Ex. A, Case Specific Opinion No. 1. (ii) "Portions of the TVT device failed to incorporate into Mrs. Ridgley's surrounding tissues;" *Id*. (iii) "Mrs. Ridgley's erosion in 2010 was caused by the physical properties of the TVT;" Ex. A, Case Specific Opinion No. 2. (iv) "the plastic sheath surrounding the mesh shredded during removal." *Id*.

Each of these expert opinions are sufficient evidence to raise a genuine issue of material fact as to manufacturing defect in Defendants' product caused Mrs. Ridgley's injuries.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request this Court deny Ethicon's motion for summary judgment in its entirety.

DATED: April 22, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ Rick Barreca
Attorney for Plaintiffs